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REMARKS

I. Status of the Claims

Claims 1-26 were originally filed. Subsequently, claims 1-13 (non-elected claims) and claim 26 were canceled. Claims 14-25 are pending under examination.

II. Claim Rejections

A. 35 U.S.C. §102

Claims 14-22 and 25 were again rejected under 35 U.S.C. §102(b) for alleged anticipation by Greenquist (U.S. Patent No. 4,806,312). Applicant respectfully traverses the rejection.

To anticipate a pending claim, a prior art reference must provide, either expressly or inherently, each and every limitation of the pending claim. MPEP§2131. The pending claims are directed to an apparatus comprising a molecular analyte layer and a film layer. The analyte layer comprises a molecular analyte, which has a binding site for a molecular ligand and is immobilized on a solid support. The film layer comprises a molecular ligand zone, which contains a molecular ligand. This ligand can, when the ligand zone is wet, diffusibly migrate to the ligand binding site of the analyte to produce a detectable product. Thus, one claim limitation is ***an analyte that is immobilized in one layer and specifically binds a ligand to form a complex, which in turn generates a detectable signal.***

In contrast, Greenquist describes a different multi-layer detection device for detecting specific binding between an analyte-ligand pair. This device contains a minimal of two layers: a reagent layer containing an immobilized analyte, and a detection layer containing an immobilized detection reagent, which generates a detectable signal upon interacting with the label portion of a labeled ligand that specifically binds the analyte (see column 5, lines 54-66). In the alternative, the device may contain a third layer in addition to the above-mentioned two layers: an optional layer providing a labeled reagent (*i.e.*, a label moiety attached to a ligand that specifically binds the analyte) is placed next to the reagent layer, so that the reagent layer is

sandwiched between this additional layer and the detection layer (see column 5, line 66, to column 6, line 3, and column 6, lines 18-25).

Using either one of these two designs by Greenquist, an analyte present in a liquid test sample first comes into contact with a labeled ligand (which is supplied either directly into the sample or by the optional layer). As a result, an analyte-(labeled ligand) complex forms based on their binding specificity to each other. With the test solution, the analyte-(labeled ligand) complex and any unbound labeled ligand diffuse into the reagent layer where the immobilized analyte is present. The analyte-(labeled ligand) complex can diffuse through this reagent layer into the detection layer and generate a detectable signal through the label moiety. On the other hand, the unbound labeled ligand is captured by the immobilized analyte in the reagent layer and therefore cannot diffuse into the detection layer to generate any false signal (see column 6, lines 26-57). Thus, the only detectable signal from a Greenquist device is generated from a complex between an analyte and a labeled ligand, neither of which immobilized. Indeed, both analyte and ligand have to migrate through at least the reagent layer to arrive at the detection layer in order to produce a detectable signal. While immobilized analyte is indeed present in the reagent layer, such immobilized analyte serves only to sequester excessive, unbound labeled ligand and does not participate in the formation of a signal-generating complex. In other words, Greenquist does not provide the limitation of ***an analyte that is immobilized in one layer and specifically binds a ligand to form a complex, which in turn generates a detectable signal.***

In the final Office Action of June 20, 2006, the Examiner argued that the analyte and ligand are interchangeable concepts as binding partners (last paragraph on page 3 of the final Office Action), and that the term "molecular ligand" can encompass a complex between the analyte and ligand (first paragraph on page 4). Applicant does not agree. First, the terms "analyte" and "ligand" in the pending claims are not merely equal binding partners, since they have features distinguishing one from the other. For instance, an "analyte" is immobilized to a fixed location whereas a "ligand" is capable of diffusing within a ligand zone upon wetting. These terms thus cannot be simply switch places in the claims. Second, although the term

"molecular ligand" is broadly defined in the specification, the context in which this term is used in the claims requires the interpretation that a "molecular ligand" is just a ligand alone without being in a complex with its binding partner "molecular analyte." Otherwise, the language in part (ii) of claim 14 "the molecular ligand can diffusibly migrate to the molecular ligand binding site of the molecular analyte to produce a detectable product" would make no sense at all. More importantly, even if these assertions were correct, the Greenquist reference would still fail to provide at least one claim limitation: an immobilized analyte that is part of a signal-generating complex of analyte-ligand.

As such, Applicant submits that Greenquist cannot anticipate the pending claims due to failure to provide all claim limitations. The withdrawal of the anticipation rejection is hence respectfully requested.

B. 35 U.S.C. §103

The Examiner also maintained the rejection of claims 23 and 24 under 35 U.S.C. §103(a) for alleged obviousness over Greenquist in view of Bergstrom *et al.* (U.S. Patent No. 5,436,161). Applicant respectfully traverses the rejection.

In order to establish a *prima facie* showing of obviousness, three requirements must be satisfied: all limitations of a pending claim must be expressly or impliedly disclosed by prior art references; there must be a suggestion or motivation in the art for one skilled artisan to combine the limitations; and there must be a reasonable expectation of success in making such a combination. MPEP §2143.

As discussed in the section above, Greenquist does not provide all limitations of independent claim 14, from which both claims 23 and 24 ultimately depend. On the other hand, the secondary reference by Bergstrom *et al.* was cited to supply the limitation of hydrogel, which is pertinent to claims 23 and 24 but not to claim 14. In other words, Bergstrom does not provide the missing limitations of claim 14 (which are missing limitations of claims 23 and 24 as well) that Greenquist has failed to provide. Thus, when considered together, the two cited references

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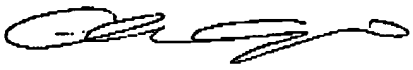
fail to provide all limitations of claims 23 and 24. As such, no *prima facie* obviousness has been established. The obviousness rejection is therefore improper and should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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